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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,725	11/19/2003	Nicholas Mazarakis	674523-2017.1	8892

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EXAMINER

MONTANARI, DAVID A

ART UNIT PAPER NUMBER

1632

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,725

Applicant(s)

MAZARAKIS ET AL.

Examiner

David Montanari

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 32-34 and 36 is/are pending in the application.
- 4a) Of the above claim(s) 35, 45 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 32-34 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/20/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant arguments and amendments filed 9/14/2006 have been entered.
2. A new examiner has taken over prosecution of the instant application.
3. Reference AX on the IDS filed on 9/20/2006 has been considered, however a line has been drawn through the reference since it cannot be published.
4. The rejection of claims 1-5, 7-9, 32, and 34 under 35 USC 102(f) is withdrawn.
5. Claims 1-9, 32-34, and 36 are examined in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention for reasons of record in the office action mailed 6/14/2006.

The claims are drawn to a method of delivering a lentiviral vector psuedotyped with a mutant, variant, homologue or fragment of a rabies G protein, comprising an NOI, such as GDNF to a target site. The claims encompass a genus of rabies G proteins, mutants, variants, homologues or fragments.

Response to Arguments

Applicant argue in amendment filed 9/14/2006 that the specification describes rabies G proteins beginning at pg. 34 line 10 and are known in the art. This is not persuasive. As discussed in the previous office action, possession of any rabies G envelope protein has not been provided for by the instant specification. Further, G proteins as a class, is huge, and encompasses thousands of species of G proteins. Applicants have not provided for any specific G protein in this case, other than describing a specific G protein encoded for by SEQ ID NO: 4. Thus for reasons of record and above the rejection is maintained.

Claims 1-9, 32-34 and 36 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of delivering a NOI to a target site, comprising the administration of an EIAV vector (pONY8z) pseudotyped with a rabies G protein selected from ERAwt, ERAsm, ERA_{adm}, or CVS, comprising a NOI to a target site, does not reasonably provide enablement for a method of treating any motor neuron disease in a patient, a method of delivering a NOI or a method of expressing a NOI, comprising administration of any lentivirus psuedotyped with a rabies G protein, such as a rabies G protein mutant, variant, homologue or fragment, comprising any NOI, such as SMN-1, GDNF, IGF-1 or VEGF. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims for reasons of record in the office action mailed 6/14/2006.

Response to Arguments

Applicants argue in amendment filed 9/14/2006 that the claims are enabled for their full scope. Applicants continue that the claims are limited to treating motor neuron disease, and that the examiner erroneously grouped Parkinson's disease with motor neuron disease. Applicants continue that gene therapy is quite different from protein therapy to which the examiner refers, and further the applicant provides data by Palfi et al. that lentiviral-mediated gene therapy has resulted in positive treatment. Applicants continue to argue that they have developed several preclinical products for the treatment of motor neuron disease, and have reported therapeutic results in art recognized models of ALS and SMA. These arguments are not persuasive. The claims encompass treating any motor neuron disease in any patient using gene therapy. Further the claims are drawn to using any NOI. The sheer breadth of any NOI is virtually unlimited. The skilled artisan could use a NOI from different species of mammals, plants, insects etc. This alone would require an undue amount of experimentation without a predictable degree of success for the skilled artisan. Applicants argue that they have had positive results in ALS, SMA mouse models of motor neuron disease, and accordingly a scope of rejection was made. Applicants have provided specific NOI's that are known to be involved in motor neuron disease, not just any NOI's but ones related specifically to motor neuron disease. The claims are not enabled for treating any motor neuron disease, and have been limited to specific NOI's associated with motor neuron disease. At best the application teaches ALS-VEGF, and SMA-SMN-1 relationships with regard to motor neuron disease treatment, not any NOI and any disease. Thus for reasons of record and above the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7-8, 32 and 34 remain rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No 6,818,209 (11.16.2004), given priority to (7.17.1998) hereafter referred to as Mitrophanous et al. for reasons of record in the office action mailed 6/14/2006.

Response to Arguments

Applicants argue in amendment filed 9/14/2006 that the Mitrophanous reference is not by another. Applicants argue that Mitrophanous and the instant application share common inventors and are commonly assigned. This is not persuasive. Applicants are advised to consult 2136.04 [R-1] of the MPEP which states:

“Another” means other than applicants, In re Land, 368 F.2d 866, 151 USPQ 621 (CCPA 1966), in other words, a different inventive entity. The inventive entity is different if not all inventors are the same. The fact that the application and reference have one or more inventors in common is immaterial. Ex parte DesOrmeaux, 25 USPQ2d 2040 (Bd. Pat. App. & Inter. 1992)”.

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In the instant case, not all of the inventors are the same and thus Mitrophanous et al. is a different inventive entity. Applicants are advised to consult 2136.05 of the MPEP to overcome this rejection. Thus for reasons above and of record the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 7-8, 32 and 34 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/838,906 for reasons of record in the office action mailed 6/14/2006.

Response to Arguments

Applicants argue in amendment filed 9/14/2006 that the claims of application 10/838,906 are not species to the present claims. Applicant continue to argue that the method claims of 10/838,906 are directed to therapy of injured nervous tissue by promotion of nervous tissue growth, which is different from the instantly claimed method of treating motor neuron disease.

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This is not persuasive. At issue is the NOI delivered, and in this case the NOI, RARbeta2 disclosed in 10/838,906 is a species of a larger genus to the rabies-g envelope proteins of the instant claims. The outcomes may be different, however it would still be obvious to the ordinary artisan to use a more defined species in a known genus, in this case rabies-g proteins. Thus for reasons of record and above the rejection is maintained.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-Tr 8-6.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari, Ph.D.


SUMESH KAUSHAL, PH.D.
PRIMARY EXAMINER